Methods of Placement of Neurostimulation Lead, Infusion Catheter, and/or Sensor via the Vasculature to the Brain

Author(s): **Disclosed Anonymously**

IP.com number: **IPCOM000012135D**

IP.com Electronic Publication: **April 10, 2003**

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Background and Summary

Millions of individuals suffer from the painful physical and emotional effects of epilepsy, chronic pain syndromes, spasticity, mood disorders, anxiety disorders, and certain types of dementia. Medical practitioners can effectively treat these maladies and lessen their harmful effects through various procedures. Deep brain stimulation and drug delivery to areas within the brain using neurostimulation leads and catheters are two treatments that may help patients with these maladies. Unfortunately, implementation of these treatments requires invasive stereotactic procedures that are often cumbersome, painful, and detrimental to patients.

Current implantable neurostimulation devices (e.g., spinal cord stimulators, deep brain stimulators) typically use leads to deliver an electrical stimulus from an implantable pulse generator (IPG) at the proximal end of a lead to an electrode(s) at the distal end of the lead. In spinal cord stimulation (SCS), the lead typically contains an electrode array.

SCS electrode arrays are typically positioned by insertion of the lead between vertebral bodies into the spinal column. SCS electrode arrays are usually positioned in an extradural location, although in the past, some researchers have placed them inside the dura through a small incision. Similarly, in motor cortex and cerebellar stimulation, the lead is placed through a small opening in the skull, and the electrode or electrode array may rest in an extradural location or may be positioned beneath the dura via a small incision.

Deep brain stimulation electrodes are conventionally placed inside the skull with the aid of a stereotactic frame. A stereotactic placement procedure requires that the physician cut through the skin, skull, dura mater, and brain parenchyma to ultimately reach a desired target. The target site is located through reference to pre-surgical diagnostic images and via intraoperative microelectrode electrical stimulation and recording. Conventional stereotactic frames are large, external metal frames that mount directly on a patient's skull with sharp, pointed metal contacts that penetrate the skin. Stereotactic frames are used, among other purposes, to guide and steady instruments during a procedure. Unfortunately,

stereotactic procedures may require several hours, can cause permanent damage, and are typically very uncomfortable for the patient.

Pacemaker and implantable cardiac defibrillator leads are usually placed through a vascular approach to the cardiac tissue, rather than a direct approach that penetrates through the bone and tissue of the thoracic cavity. This vascular approach, in contrast to the stereotactic procedure, requires significantly less time and is typically more comfortable for the patient. In such a procedure, access to the vasculature may be gained through a major vessel, e.g., the femoral vein or artery or the subclavian vein or artery. Typically, a flexible lead bolstered by a rigid stylet allows the electrodes to be snaked through the vasculature to the appropriate location, e.g., an atrium or ventricle.

U.S. Patent No. 6,006,134 to Hill, et al. discloses several aspects of a system for regulating the heartbeat where an intravenous lead stimulates nerve fibers of the heart, and electrodes and catheters are delivered intravenously. The '134 patent teaches delivering a lead with electrodes through the vascular system to vascular sites where the electrodes may stimulate neighboring vagus, hypoglossal, phrenic, parasympathetic, and sympathetic nerve fibers. The area of vagus nerve fibers intended to be stimulated in the '134 patent is below the cranium. Further, the '134 patent teaches positioning of leads with electrodes within an azygous vein, a hemizygous vein, and an internal jugular vein below the cranium. The use of these veins and stimulation of these nerve fibers in the '134 patent are intended to control the beating of a heart. The '134 patent does not teach delivery of leads or catheters through the vasculature to target sites located within the brain, where glial cells may be stimulated.

U.S. Patent No. 5,755,766 to Chastain, et al. discloses an open-ended intravenous cardiac lead that follows the path of a guidewire, upon which the lead is threaded through the cardiac vasculature. The '766 patent does not teach delivery of leads or catheters through the vasculature to target sites located within the brain.

Both of the above patents have disclosed technology related to vascular delivery primarily in the cardiac region. Neither of the above patents has incorporated procedures for delivery of medical devices through the vasculature to target sites within the brain. Further, the traditional stereotactic procedure does not allow for vascular delivery in the brain. Rather, stereotactic procedure requires

direct insertion of medical devices into the brain, penetrating through and often permanently damaging the skin, skull, dura mater, and brain parenchyma of patients. Hence, there is a need for a method for delivery of medical devices such as leads, catheters, and/or sensors via the vasculature to the brain.

The present invention provides a method for delivery of medical devices such as leads, catheters, and/or sensors via the vasculature to the brain. The methods of the present invention provide less invasive and less cumbersome procedures for patients and physicians than traditional stereotactic procedures.

More specifically, the present invention provides methods for placing a lead(s) for neurostimulation, specifically deep brain stimulation, via the vasculature. The present invention also provides methods for placing an infusion catheter(s) via the vasculature to facilitate targeted application of drugs to neural tissue. The present invention also provides methods for placing a sensor(s) via the vasculature near neural tissue for detection of electrical, chemical, or other activity.

Detailed Description

The present invention provides methods for placing a neurostimulation electrode(s), an infusion catheter(s), and/or a sensor(s) adjacent neural tissue (including nerve fibers and glial cells) of the brain via the vasculature, also described herein as delivering a medical device to a target site. As used herein, "adjacent" and "to a target site" mean as close as reasonably possible to target tissue(s), including touching or even being positioned within the tissue, but in general, may be as far as about 500 mm from the target tissue. An electrode lead, a sensor lead, and/or a catheter that is relatively small and flexible may be left chronically in the vasculature of the brain, as is currently done with intravenous cardiac leads. A lead and/or catheter of the invention may be inserted through the skin and into the vasculature at a number of vascular access points in the body, as discussed below. While the lead and/or catheter may be flexible, it may be associated with a stylet and/or guidewire (or other similar device) that provides rigidity during its course through the vasculature during the implantation procedure. The lead and/or catheter may also include a means of fixation, so that it may be chronically anchored adjacent to a target site, as discussed below.

A number of neural structures may be accessed via the vasculature, as such structures are adjacent vascular structures. For instance, a number of large veins course through the brain adjacent structures that have demonstrated therapeutic efficacy in certain disorders in response to electrical stimulation and/or drug infusion.

Referring now to FIG. 1, the relatively large vein known as the straight sinus 100 lies between the cerebral cortex and the cerebellum, along the midline. A lead, catheter, or sensor in straight sinus 100 may allow relatively easy access to the midline cortex and cerebellum. The superior veins of the cerebellum and the superior veins of the vermis drain blood from the superior areas of the lateral hemispheres of the cerebellum and the upper region of the vermis, and thus they provide venous access to a large part of the cerebellum. The superior sagittal sinus 110 and the great cerebral vein (of Galen) 120 are very large venous structures that course through the midline of the cerebral cortex, allowing easy access to midline cerebral structures.

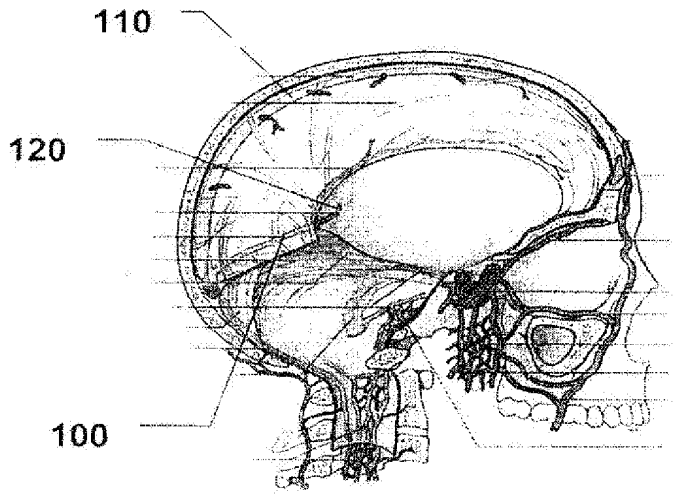

FIG. 1

Referring now to FIGS. 2A-2B, the superior thalamostriate vein 200 runs along the choroid plexus of the lateral ventricle in the groove between the thalamus and the caudate nucleus into the internal cerebral vein, thus providing relatively easy venous access to portions of the thalamus, caudate nucleus, and choroids plexus. The internal cerebral veins 210 are paired veins running from the interventricular foramen (of Monro) along the roof of the third ventricle, adjacent to the thalamus. The basal vein (Rosenthal's vein) 220 is a large vein originating at the anterior perforated substance (a.k.a., olfactory tubercle); it runs along the optic tract and around and behind the brainstem, draining into the great cerebral vein 230. Basal vein 220 offers relatively easy access to portions of the brainstem, the thalamus, and the inferior cortex for electrical stimulation and/or drug infusion. Electrical stimulation of and/or drug infusion to portions of the thalamus may provide effective therapy to patients with chronic pain syndromes, movement disorders, and/or epilepsy.

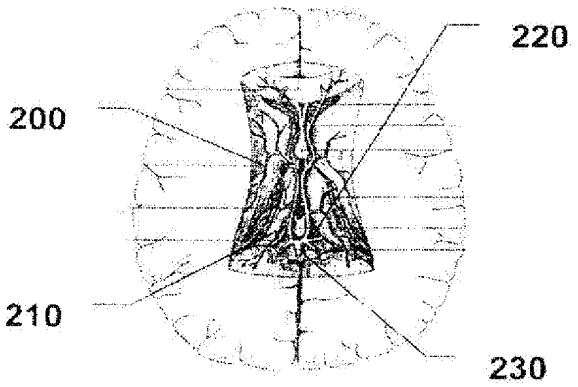

FIG. 2A

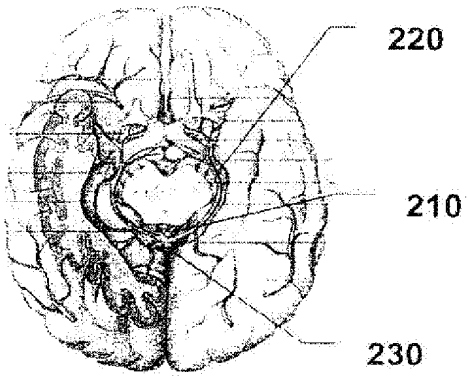

FIG. 2B

Referring now to FIG. 3, the superficial superior cerebral veins 300 and the superior anastomotic veins 310 lie near the surface of the sensory and motor cortical regions. Electrical stimulation of and/or drug infusion to these areas has been investigated for the treatment of chronic pain syndromes.

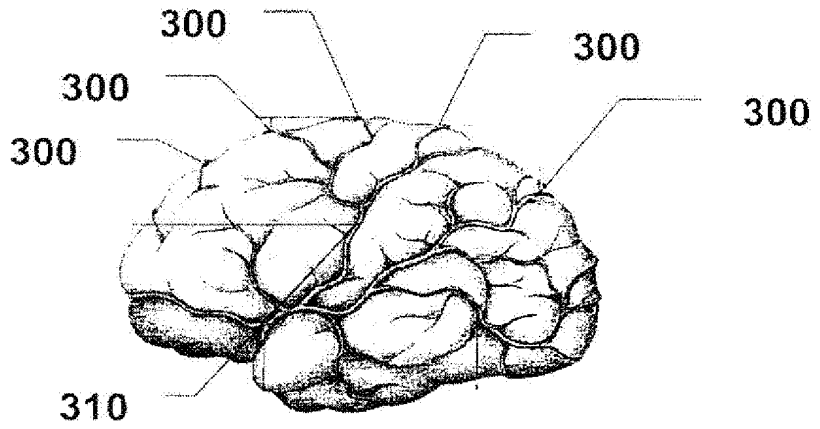

FIG. 3

Referring now to FIG. 4 and FIG. 5, the anterior cerebral arteries and veins course through the parenchyma of the frontal lobes. The prefrontal veins and frontal veins also drain blood from the frontal cortex (into the superior sagittal sinus 110). These offer relatively easy access to the frontal lobe through large venous structures. Electrical stimulation of and/or drug infusion to the frontal lobes has been investigated as treatment for various disorders, including epilepsy and mood disorders. The middle cerebral artery 400, the posterior cerebral artery 410, the veins of the parietal lobe 500, the veins of the occipital lobe 510, and the basal veins 220 allow relatively easy access, through large venous structures, for electrical stimulation of and/or drug infusion to the parietal, temporal, and occipital lobes.

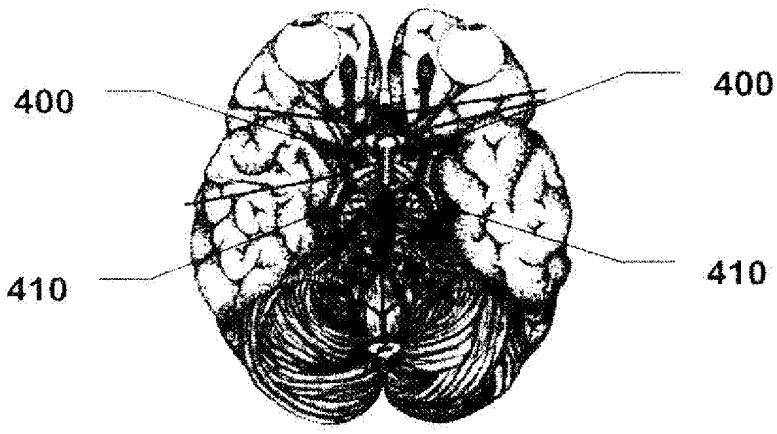

FIG. 4

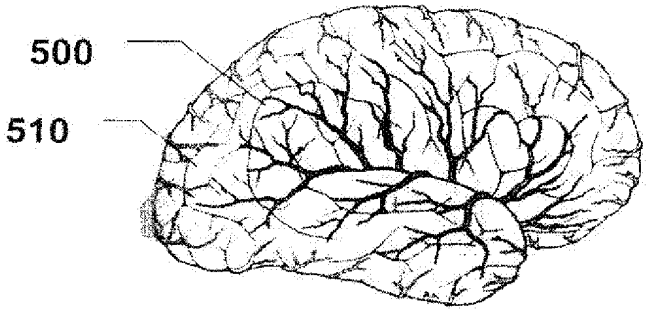

FIG. 5

In cardiac procedures, access to cardiac structures is initiated in relatively large veins or arteries, e.g., the femoral vein, subclavian vein, or the external jugular vein usually via a large catheter, e.g., a femoral access catheter. Initial access is gained by incision through the skin to the vasculature. For example, the standard Seldinger technique starts with an 18-gauge needle that is inserted into a vein (e.g., the subclavian vein, possibly via the cephalic vein). A J-tipped guidewire is placed into the needle and then is placed into the vein through the needle. The needle is then removed over the guidewire. The guidewire is then used for insertion of a dilator that is located within a lumen of an introducer sheath. The dilator also includes a lumen, allowing the dilator and introducer sheath to be pushed onto the J-tipped guidewire, through the tissue, and ultimately into the vein and finally into the superior vena cava. At this point, the dilator and the J-tipped guidewire are pulled out of the lumen of the introducer sheath. Next, the lead is placed through the lumen of the introducer sheath into the target location. The lead may be driven through the introducer and vasculature by means of a stylet or guidewire. In the case of a stylet, the stylet may be placed in an internal lumen of the lead and is prevented from advancing beyond the distal end of the lead by a distal tip, thereby "driving" the lead through the vasculature. In the case of a guidewire, the guidewire may be placed in an internal lumen of the lead and advanced beyond the distal end of the lead through a hole in the distal tip. With the assistance of fluoroscopy, the guidewire snakes through the vessels to the target location; then, the lead is pushed over the guidewire to the same location. In addition, the guidewire might incorporate an electrode at the distal tip. A guidewire electrode may allow recording and/or stimulation of tissue to verify that the guidewire electrode is in the correct stimulation location prior to placement of the lead's electrode(s) at the same location.

In an embodiment of the invention, a subclavian vein or artery may be used as the initial access point to a target site of the brain vasculature. Alternatively, one of the jugular veins or the carotid arteries may be used as the access point. However, any convenient access point may be used, e.g., a femoral vein or artery. In some situations, venous access may be chosen over arterial access, such as when arterial blockage or damage may rapidly lead to hypoxic damage and death of neural and other structures. In other situations, such as an electrode placement procedure performed along with a surgery involving an artery or arteries (e.g.,

carotid endarterectomy), arterial access may be chosen. Arterial access might also be utilized when the arteries feeding a structure are much closer to a target site and/or are much larger than nearby venous structures.

In an embodiment of the invention, coating the outer surface of the lead and/or the outer surface of the guidewire (or other similar structure) may facilitate placement of the lead. For example, the outer surface of the lead could be coated with a hydrophilic agent such as polyvinylperolydone (PVP). The guidewire could be coated with an agent such as, but not limited to, PVP, Teflon®, or heparin to facilitate placement in the vasculature.

Electrical stimulation in the vasculature may prove less efficient than stimulation directly in, for example, the brain parenchyma itself (as in Deep Brain Stimulation). Some electrical current may be shunted by the blood, and/or some may be blocked or shunted by the vascular endothelium. However, SCS electrodes typically stimulate through dura and cerebrospinal fluid (CSF), which may be expected to offer a similar shunting and/or blocking of current; yet, this SCS stimulation is effective. Electrical stimulation of vasculature may cause contraction of the smooth muscle around a vessel, thereby decreasing the size of the vessel lumen. This effect is likely to be more pronounced in arterial vessels, as they typically are surrounded by significantly more smooth muscle than veins. However, this smooth muscle contraction may be less of a risk in the brain, as the body regulates blood flow to the brain very well, and may compensate for changes in lumen diameter caused by electrical stimulation.

After arriving at a vascular target site, the lead, catheter, or sensor, or a portion or auxiliary component thereof, may also exit through the wall of the vasculature to be implanted in an adjacent target. This exit may be accomplished by, but not limited to, either of the following two procedures: pushing or forcing a lead with a stiffening member inserted, such as a stylet, through a vascular wall or, alternatively, by using a mechanical device to drive the lead sideways from the main lead, such as is done with a dye-injecting catheter in Endoscopic Retrograde Cholangiopancreatography (ERCP). Such insertion through a vascular wall may reasonably be expected to cause trauma to the vasculature and surrounding tissue. The trauma may be reduced by insertion in relatively low-pressure vasculature (i.e., veins) and/or by insertion of relatively small leads (e.g., less than about 1 mm in

diameter). In addition, agents such as steroids may be coated on the surface of the lead that enters the surrounding tissue to help reduce inflammation.

The lead(s) and/or catheter(s) may be connected to a system control unit (`SCU) at or near the initial access point, or the lead(s) and/or catheter(s) may be tunneled to another point in the body for connection to an SCU. The SCU may control the stimulation, infusion, and/or sensor parameters, or it may coordinate such control with other devices. For instance, the SCU may use sensed data to adjust stimulation and/or infusion parameters, or it may relay sensed data to other devices.

If necessary or desired, implanted electrode leads, infusion catheters, and/or sensor leads may be anchored in the vasculature near the target site. An anchoring device(s) similar to or of the type used in cardiac leads may be used. For instance, leads may include tines. However, these structures may cause obstruction of blood flow and/or make it difficult or impossible to remove the lead, if ever desired. Thus, bends may be provided in the lead for anchoring the lead in the vasculature of the brain, in addition to forcing the electrodes in closer proximity with the target tissue. These bends may also be useful for guiding the lead through the tortuous turns of the vasculature.